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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES - CENTRAL CIVIL WEST

Coordination Proceeding Special Title (Rule 3.550) **BYETTA® CASES**	JCCP No. 4574 **DEFENDANTS' REPLY IN RESPONSE TO REQUEST FOR ADDITIONAL BRIEFING ON THE ISSUE OF PREEMPTION** Judge: Hon. William F. Highberger Dept.: 322

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1. Plaintiffs' Submission has nothing to say about the most relevant case law. It is not correct, as Plaintiffs assert, that "cases specifically addressing impossibility preemption after *Levine* are . . . scarce."[1] There are at least 19 such cases, not including *Wyeth v. Levine* itself. Nor is it correct, as Plaintiffs assert, that "Defendants have cited no case that interprets *Levine* to assign the 'clear evidence' of impossibility test to the Court alone, as a matter of law."[2] Defendants cite all 19 cases (at notes 4, 5 & 6 of their Response). In ***none*** of those cases did the court submit the "clear evidence" question to a jury and in ***each*** the court decided the question as a matter of law.[3] Nor is it correct, as Plaintiffs also assert, that "Defendants ask the court to do something no court before has done."[4] Defendants ask the Court to do what ***every*** one of these 19 courts—plus the trial court, the Vermont Supreme Court, and the U.S. Supreme Court in *Wyeth v. Levine*—has done in applying the "clear evidence" standard.

2. Plaintiffs' Submission does not cite ***any*** of the 19 cases.[5] Instead, Plaintiffs begin their Submission with a discussion of *Brown v. Earthboard Sports, USA, Inc.*, 481 F.3d 901 (6th Cir. 2007), a case that does not involve prescription drugs, FDA regulations, or even failure-to-warn

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[1] Plaintiffs' Submission in Response to Court's Request for Further Briefing in Connection with Preemption ("Pls. Submission") at 5 n.4.

[2] *Id.* at 2.

[3] Plaintiffs' Submission identifies a 20th case, *Estate of Cassel v. ALZA Corp.*, No. 12-cv-771-wmc, 2014 U.S. Dist. LEXIS 27924 (W.D. Wis. Mar. 5, 2014). Like the other cases that deny a defendant's motion for summary judgment on the ground of preemption, it did so, not because there were disputed issues of fact, but because it determined as a matter of law that the defendants' evidence did not add up to "clear evidence." Indeed, the court concluded that "defendants have offered *no* evidence that the FDA would have exercised its authority to prohibit defendants from creating and submitting such a design for approval." *Id.* at *17-18 (emphasis in original).

It is noteworthy that the court, like the MDL court here, deferred the summary judgment motion to permit the parties to take discovery and develop a factual record. *Id.* at *2. Then the court decided the motion based on the "Undisputed Facts," *id.* at *2 & n.2, as a matter of law.

[4] *Id.* at 9.

[5] *See* Pls. Submission at 1-6 (answering the questions, "Is the Determination of Whether Federal Impossibility Preemption Applies to a Given Case a Question of Law for the Court or a Question of Fact for the Jury?" and "Does the Court or Jury Resolve Disputed Facts on This Issue?").

claims, and that was decided two years before *Wyeth v. Levine*.[6] It is rather late in the game to argue that *Brown*, not *Wyeth v. Levine*, defines the test for conflict preemption. Plaintiffs' reliance on *Brown*, involving the preemptive effect of federal securities law, cannot be reconciled with their statement that "different preemption questions demand different analyses."[7] The cases here demand the preemption analysis for prescription drug, failure-to-warn cases set forth in *Wyeth v. Levine* and applied in the 19 cases ignored by Plaintiffs.

3. Plaintiffs' Submission is correct that *Wyeth v. Levine*'s "history illustrates the interplay of fact and law."[8] But the Submission gives a garbled account of that history which misses the whole point: the trial court did not instruct ***the jury*** to decide whether it was impossible for Wyeth to comply with both state-law and FDA labeling requirements; the trial court decided that issue ***itself*** as a matter of law "[i]n a summary judgment motion prior to trial, as well as in [a] timely motion for judgment as a matter of law following trial." *Levine v. Wyeth*, 944 A.2d 179, 183 (Vt. 2006), *aff'd*, 555 U.S. 555 (2009).[9] Stating that "preemption is a question of law," the Vermont Supreme Court reviewed the trial court's decisions de novo and affirmed, in part because "[t]he record lack[ed] any evidence that the FDA was concerned that a stronger warning was not supported by the facts . . . ." *Id.* at 184, 188. Wyeth argued that the regulatory history of the labeling reflected FDA's opinion that a stronger warning was unnecessary. *Id.* at 188-89. But the court reviewed that history for itself and held that "[t]he record does not support this

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[6] *Id.* at 1-2. In *Brown*, the question before the court was whether federal securities laws preempted a claim under the Kentucky Blue Sky law for the unlawful sale of an unregistered security. 481 F.3d at 905.

[7] Pls. Submission at 3. Plaintiffs argue that different preemption analyses apply in different contexts in an effort to distinguish *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1089 n.10 (2008), in which the California Supreme Court said that "federal preemption presents a pure question of law," and *Spielholz v. Superior Court*, 86 Cal. App. 4th 1366, 1371 (2d Dist. 2001), in which the court of appeal also said that "[p]reemption is a legal issue." *See* Pls. Submission at 3-4.

[8] Pls. Submission at 2.

[9] The trial court instructed the jury regarding FDA labeling requirements only as to the issue of negligence. *Levine*, 944 A.2d at 182 ("The court instructed the jurors that they could consider the FDA's approval of the label in use at the time of plaintiff's injury, but that the label's compliance with FDA requirements did not establish the adequacy of the warning or prevent defendant from adding to or strengthening the warning on the label.").

interpretation." *Id.* at 189. The court, not the jury, considered this evidence in light of the test for preemption.

4. Here, after a year of discovery largely devoted to preemption, the material facts are not in dispute. Plaintiffs' Submission is correct that the cases concerning preemption in the context of prescription drugs typically recite the "long and robust" regulatory history of the drug's labeling[10]—what Plaintiffs call the "dialogue" between FDA and the manufacturer about the labeling[11]—and examine that history to determine whether it adds up to "clear evidence" that FDA would have disapproved a stronger warning. But here, too, there is a robust regulatory history—seven FDA statements or actions in 2014—which provides the factual foundation for a determination that there is "clear evidence" that FDA would not have approved, then or earlier, a pancreatic cancer warning. The ***fact*** of these seven statements or actions—that FDA made the statements and took the actions it did—cannot truly be in dispute, and Plaintiffs' Submission does not dispute that fact.

Rather than dispute that FDA made any statement Defendants claim it made, or took any action that Defendants claim it took, Plaintiffs dispute (i) what legal significance should be given to FDA's statements and actions and (ii) whether they add up to "clear evidence," saying that the FDA statements cited by Defendants "are more perplexing than discouraging."[12] Plaintiffs are wrong on both counts, however. First, preemption is a matter of law, as the federal and California courts have long understood and held. Thus, as *Wyeth v. Levine* and its progeny make clear, the court determines whether the undisputed facts add up to "clear evidence." "Clear evidence," in short, is the legal conclusion that either can or cannot be drawn from the material facts, which almost invariably are the regulatory history of FDA's statements and actions.[13] If "clear evidence" were itself a factual question, not a legal conclusion, then there would be no role for the

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[10] Pls. Submission at 10.

[11] *Id.*

[12] *Id.* at 9.

[13] Plaintiffs misstate the *Wyeth v. Levine* test. It is not "whether the facts *indisputably* establish that the FDA would have prohibited the Defendants from adding language about pancreatic cancer." *See id.* at 2 (emphasis added). "Clear evidence" need not be indisputable evidence.

court—a result that cannot be squared with the established principle that preemption is a matter of law and the consistent line of cases applying *Wyeth v. Levine*.

Second, as Dr. Fleming's testimony makes clear, FDA's statements about a pancreatic-cancer warning are not at all "perplexing." Dr. Fleming admitted that FDA reached the two fundamental conclusions that are dispositive for this motion: that the scientific data do not meet the regulatory threshold for an additional warning (1) in the "Warnings" section of the labeling or (2) in the "Adverse Reactions" section.[14] On these critical points, ***the record*** is undisputed, not only as to the underlying facts, but also as to the meaning of those facts. Plaintiffs' counsel can assert that "the FDA hasn't made up its mind," but ***the record***, which includes Dr. Fleming's admissions, establishes that FDA conducted a robust review of the scientific data concerning pancreatic cancer and concluded that the current labeling is adequate, because the data are inconsistent with assertions of a causal association—indeed, that "any suspicion of causal association . . . is indeterminate at this time."[15]

5. Thus, in the first instance, Defendants' motion for summary judgment is ripe for decision, because the material facts regarding what FDA has said, done, and concluded about the drugs' labeling are undisputed. Second, even if there were a dispute about one of the seven events that Defendants contend add up to "clear evidence"—about, for example, what FDA said in the briefing book about a pancreatic-cancer warning—the motion remains ripe for decision. Less than all seven events, even The New England Journal of Medicine assessment alone, constitute "clear evidence" that FDA would have disapproved a pancreatic-cancer warning. Third, if it were necessary to resolve a question of underlying fact about what FDA had said or done, the Court could do so. The likelihood of a factual dispute about what FDA has said or done is small; after all, there is no indication of any such dispute in *Wyeth v. Levine* or the cases that have applied it. But if, hypothetically, FDA had communicated disapproval of a proposed labeling change in a telephone call, and two memoranda recorded that communication differently, the Court could reconcile the memoranda, or decide which memorandum provided the more

[14] Fleming Dep. at 153:11-19; 153:20-154:3.

[15] *See, e.g.*, Fleming Dep. at 92:13-16; 107:2-6; 108:2-5; 127:11-19; Fleming Rpt. at 29.

reliable account. The California Evidence Code authorizes such preliminary fact finding,[16] and the courts routinely resolve such disputes with regard to facts relevant to personal or subject matter jurisdiction. The courts also resolve such disputes with regard to whether an activity is abnormally dangerous for reasons that apply in the context of preemption as well.

Conclusion

It is well-established that preemption is a question of law. This axiom means that the court, not a jury, draws the conclusion in a given case whether the facts meet the applicable test for preemption. The applicable test here is whether there is clear evidence that FDA would have disapproved a different warning. And, as *Wyeth v. Levine* and the cases applying it make clear, the court draws the conclusion whether the facts add up to clear evidence of what FDA would do. The material facts here are seven FDA statements and actions reflecting the agency's evaluation of the pancreatic cancer risk and the adequacy of the current labeling. Because what FDA has said and done is undisputed—and, indeed, because Plaintiffs' expert has admitted the legal significance of those statements and actions—the Court should grant Defendants' motion for summary judgment.

[16] *See* Cal. Evid. Code § 310 ("issues of fact preliminary to the admission of evidence are to be decided by the court"); § 400 ("preliminary fact" issues decided by the court include issues that go to "the admissibility or inadmissibility of evidence" including "the qualification or disqualification of a person to be a witness and the existence or nonexistence of a privilege"). As the Evidence Code Analysis explains, "Section 400 distinguishes those preliminary facts upon which the admissibility of evidence depends from those facts sought to be proved by that evidence." California Evidence: 2014 Courtroom Manual (LexisNexis).

Dated: October 8, 2015

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